

**Notice of Allowability**

Application No.

08/653,114

Examiner

Richard Schnizer, Ph. D

Applicant(s)

FALCK-PEDERSEN, ERIK S

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment filed 1/12/04.
2. ☒ The allowed claim(s) is/are 1,3,4,9, 17-20, and 23.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☒ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☒ to Paper No./Mail Date 12.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

### **EXAMINER'S AMENDMENT**

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/12/04 has been entered.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Heather Kissling on 3/7/04.

The application has been amended as follows:

#### **IN THE SPECIFICATION:**

In the first sentence of the application, insert --(abandoned)-- immediately after "Serial No. 08/166,925, filed on December 14, 1993".

At page 35, line 32, delete "plaguing" and substitute --plaquing-- therefor.

At page 40, line 19 delete "Wity" and substitute --With-- therefor.

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IN THE CLAIMS:

Claim 1. (Currently Amended) An adenoviral vector for expressing a heterologous gene(s) in a host cell, the adenoviral vector comprising [in the] an adenoviral E1 region, wherein said adenoviral E1 region comprises the following in 5' to 3' order: a heterologous promoter; a eukaryotic splice acceptor site; a eukaryotic splice donor site; at least one insertion site for cloning a selected heterologous gene[,]; and [, in an orientation opposite to the direction of transcription of the adenoviral E1 region (a) a heterologous promoter positioned upstream from said at least one insertion site, wherein, upon cloning of the selected heterologous gene into said at least one insertion site, said gene is under the regulatory control of said heterologous promoter; (b) a eukaryotic splice acceptor and splice donor site positioned downstream of said promoter and upstream of said at least one insertion site; and (c)] a polyadenylation sequence [positioned downstream of said insertion site], wherein the heterologous promoter is oriented to drive transcription of the heterologous gene in a direction opposite to the direction of transcription of the adenoviral E1 region.

Claim 20. (Currently Amended) A method of delivering a heterologous gene to an animal heart *in vivo*, wherein the method comprises administering to the animal heart an adenoviral vector comprising[, in the] an adenoviral E1 region, [and in an orientation opposite to the direction of transcription of the adenoviral E1 region (a) a heterologous gene; (b) a promoter positioned upstream from the heterologous gene, the heterologous gene being under the regulatory control of the promoter; (c) a eukaryotic splice acceptor and donor site positioned downstream of the promoter and upstream of the

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heterologous gene; and (d) a polyadenylation sequence] wherein said adenoviral E1 region comprises the following elements in 5' to 3' order: a heterologous promoter; a eukaryotic splice acceptor site; a eukaryotic splice donor site; heterologous gene, and a polyadenylation sequence, wherein the heterologous promoter is oriented to drive transcription of the heterologous gene in a direction opposite to the direction of transcription of the adenoviral E1 region.

Add the following claim:

23. A method of delivering a heterologous gene to an animal *in vivo*, wherein the method comprises administering to the animal an adenoviral vector comprising an adenoviral E1 region, wherein said adenoviral E1 region comprises the following elements in 5' to 3' order: a heterologous promoter; a eukaryotic splice acceptor site; a eukaryotic splice donor site; heterologous gene; and a polyadenylation sequence, wherein the heterologous promoter is oriented to drive transcription of the heterologous gene in a direction opposite to the direction of transcription of the adenoviral E1 region.

### ***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance: Applicant's amendment overcomes the rejection of record. While there was ample motivation at the time of the invention to insert into an adenoviral E1 region an expression cassette comprising an intron, the art at that time did not teach or suggest insertion of expression cassettes oriented antiparallel to the direction of transcription of E1 transcripts. The

Examiner's amendment makes clear that all the elements of the expression cassette are located in E1. New claim 21 was added at Applicant's request and is free of the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 571-272-0564.

  
DAVE T. NGUYEN  
PRIMARY EXAMINER

Richard Schnizer, Ph.D.